Section 5 – 510(k) Summary

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OCT 18 2013

Official Contact: Ferenc Dahnér – Regulatory Affairs Manager

Proprietary or Trade Name: Provox® Vega™ Puncture Set

Common/Usual Name: Voice Prosthesis

Classification Class II - 21 CFR 874:3730

Classification Name/Code: Prosthesis, Laryngeal (Taub) / EWL

Device: Provox® Vega™ Puncture Set

Predicate Devices: Atos Medical – Provox® Vega™ Voice Prosthesis with SmartInserter – (K090455)

Atos Medical - Provox Voice Prosthesis – (K940638)

Device Description:

The Provox Vega Puncture Set is a device for creating a primary or secondary TE puncture, with subsequent dilatation of that puncture to a width that facilitates placement of the included Provox Vega voice prosthesis. The Provox Vega voice prosthesis is preloaded on the Puncture Dilator, which is part of the device.

The Provox Vega Puncture Set is intended for single use only and the package contains the following sterile items in a blister package:

- 1 Pharynx Protector (Fig. 1:1) made of transparent thermoplastic,
- 1 Puncture Needle (Fig. 1.2) made of surgical stainless steel,
- 1 Guidewire (Fig. 1.3) made of pre-colored fluoroplastic,
- 1 Puncture Dilator with 1 preloaded Provox Vega voice prosthesis (Fig. 1.4). The Puncture Dilator is made of thermoplastic elastomer and polypropylene; and the Vega voice prosthesis is made of medical grade silicone rubber and fluoroplastic.

The set also includes the following non-sterile items:
- 1 Instructions for use - Provox Vega Puncture Set,
- 1 Provox Vega Patient's Manual,
- 1 Provox Brush of a size corresponding to the voice prosthesis,
- 1 Provox Brush Instructions for Use.
- 1 Provox Plug of a size corresponding to the voice prosthesis,

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• 1 Provox Plug Instructions for Use.
• 1 Emergency Card

Indications for Use:

Provox® Vega™ Puncture Set is a device for performing a primary or secondary tracheo-esophageal (TE) puncture in laryngectomized patients, with integrated placement of a Provox Vega voice prosthesis.

The Provox Vega voice prosthesis is a sterile single use indwelling voice prosthesis intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is performed by the patient while it remains in situ.

Environments of use include;
- Provox® Vega™ Puncture Set – hospitals and sub-acute care institutions.
- Provox® Vega Voice Prosthesis – hospitals, sub-acute care institutions and home.

Patient Population: For patients who have got their larynx surgically removed.

Environment of Use:
- Provox® Vega™ Puncture Set – hospitals and sub-acute care institutions.
- Provox® Vega Voice Prosthesis – hospitals, sub-acute care institutions and home.

Contraindications: Do not use the Provox Vega Puncture Set if the patient has anatomical abnormalities that may hinder safe puncturing of the TE wall or safe voice prosthesis placement (e.g., significant stenosis or significant fibrosis at the puncture site) as this may cause tissue damage.
Do not use the Provox Vega Puncture Set for secondary TE puncture if the patient suffers from severe trismus that precludes proper protection of the pharyngeal wall. Failure to protect the pharynx during puncture may lead to unintended trauma of the pharyngeal/esophageal tissue.

Non Confidential Summary

Summary of substantial equivalence

Specification	Predicates Provox Voice Prosthesis (K940638) Provox® Vega™ Voice Prosthesis with SmartInserter – (K090455)	Proposed Provox® Vega™ Puncture Set
Indications for use	The Provox® Voice Rehabilitation System (K940638) is intended for use in surgical, prosthetic voice restoration after total laryngectomy. The Provox® Vega Voice Prosthesis (K090455) is a sterile single use indwelling voice prosthesis intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is handled by the Patient while it remains in situ.	Provox® Vega™ Puncture Set is a device for performing a primary or secondary tracheo-esophageal (TE) puncture in laryngectomized patients, with integrated placement of a Provox Vega voice prosthesis. The Provox Vega voice prosthesis is a sterile single use indwelling voice prosthesis intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is performed by the patient while it remains in situ.
Environment of Use	Hospitals, sub-acute care institutions and home	Identical
Patient Population	For patients who have got their larynx surgically removed.	Identical
Contra-indications	Severe, surgically non-correctable stenosis of the pharyngoesophageal (PE) segment and/or tracheostoma are contraindications for the use of the Provox® voice prosthesis. Radiotheraphy doses greater than 70 Gy in 7 weeks increase the risk of tissue necrosis in and around the region of the TE-fistula. Creation of a TE-fistula for prosthetic voice rehabilitation is not recommended under the circumstances.	Do not use the Provox Vega Puncture Set if the patient has anatomical abnormalities that may hinder safe puncturing of the TE wall or safe voice prosthesis placement (e.g., significant stenosis or significant fibrosis at the puncture site) as this may cause tissue damage. Do not use the Provox Vega Puncture Set for secondary TE puncture if the patient suffers from severe trismus that precludes proper protection of the pharyngeal wall. Failure to protect the pharynx during puncture may lead to unintended trauma of the pharyngeal/esophageal tissue.
Comparison of components		
Voice Prosthesis	The Provox Vega voice prosthesis (K090455) is a sterile single use indwelling voice prosthesis intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is performed by the patient while it remains in situ.	The ***Provox® Vega™ Voice Prosthesis*** included in the Provox® Vega™ Puncture Set is identical in every aspect to the voice prosthesis in the predicate Provox® Vega™ Voice Prosthesis with SmartInserter – (K090455)

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Accessory: ***Provox GuideWire***	The accessory ***Provox GuideWire*** (K940638) is a sterile single use insertion device intended for placement of a sterile Provox indwelling Voice Prosthesis after total laryngectomy (primary or secondary puncture), or for retrograde replacement of a sterile Provox indwelling Voice Prosthesis.	The ***GuideWire*** together with the Puncture Dilator and Wirelock is a modification of the previously cleared accessory GuideWire in predicate Provox Voice Prosthesis (K940638). The accessory GuideWire is also an accessory to the predicate Provox® Vega™ Voice Prosthesis with SmartInserter – (K090455)
Accessory: ***Provox® Trocar***	The accessory *Provox® Trocar* (Exempted, Product Code KAB) is an instrument for making primary and secondary TE punctures.	The ***Puncture Needle*** in the Provox® Vega™ Puncture Set is a modification of the exempted device Provox Trocar that is an instrument for performing the TE puncture.
Accessory: ***Provox® Pharynx Protector***	The accessory *Provox® Pharynx Protector* (Exempted, Product Code LRC) helps protect the pharyngeal walls from accidental piercing during primary TE puncture.	The ***Pharynx Protector*** in the Provox® Vega™ Puncture Set is a modification of the exempted device Provox Pharynx Protector that is intended to help protect the pharyngeal wall from accidental piercing during primary TE puncture.
Materials; Voice Prosthesis	Medical grade silicone rubber and fluoroplastic. Adhesive: Silicone Adhesive	Identical
Materials; ***Provox GuideWire***	ABS, PVC	***GuideWire***; pre-colored fluoroplastic Puncture Dilator; thermoplastic elastomer and polypropylene
Materials; ***Provox® Trocar***	surgical stainless steel	***Puncture Needle:*** surgical stainless steel
Materials; ***Provox® Pharynx Protector***	Stainless Steel, Aluminum, Silicone	***Pharynx Protector*** :Transparent thermoplastic

Summary:
There are no significant differences between the Provox Vega Puncture Set compared to the predicate devices in terms of indications, materials, design and operating principles. Information presented in this submission supports that Provox Vega Puncture Set is as safe and effective, and performs as well or better than the predicate devices.

Conclusion:
Atos Medical AB concludes that the Provox Vega Puncture set is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 18, 2013

Atos Medical AB
c/o Mr. Ferenc Dahnér
Regulatory Affairs Manager
PO Box 183
SE 242 22 Hörby
Sweden

Re: K131947
Trade/Device Name: Provox Vega Puncture Set
Regulation Number: 21 CFR 874.3730
Regulation Name: Laryngeal Prosthesis (Taub Design)
Regulatory Class: Class II
Product Code: EWL
Dated: September 4, 2013
Received: September 6, 2013

Dear Mr. Dahnér:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K131947

Device Name: Provox® Vega™ Puncture Set

Indications for Use:

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The Provox Vega voice prosthesis is a sterile single use indwelling voice prosthesis intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is performed by the patient while it remains in situ.

Environments of use include;

- Provox Vega Puncture Set – Hospitals
- Provox Vega Voice Prosthesis – Hospitals, sub-acute care institutions and home.

Prescription Use XX **and/or** **Over-the-counter use** __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Srinivas Nandkumar -S